

8899 '98 NOV 246 199837

October 30, 1998

Office of Special Nutritionals
HFS-450 Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C St. SW
Washington DC 20204

Statement of Nutritional Support- MEN'S PM FORMULA OVER 40 Pursuant to 21 CFR Part 101.93, American Specialty Health & Wellness (ASHW) files the following Statement of Nutritional Support for the Dietary Supplement marketed as:
MEN'S PM FORMULA OVER 40

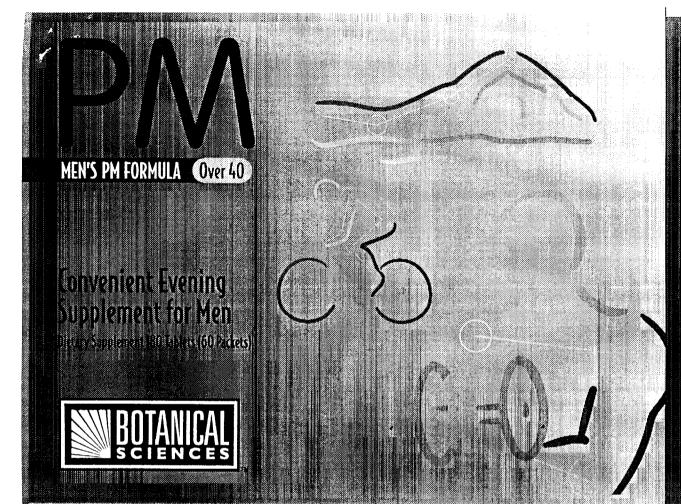
- 1) Name and Address of Distributor: ASHW 8989 Rio San Diego Dr. Ste. 250, San Diego CA 92108
- 2) Text of Nutritional Support Statement being Made: "Men's and women's AM-PM formulas contain a blend of vitamins, minerals, and herbs specifically formulated to work with your body's natural daily rhythms, so that nutrients are available when the body needs them most."
- 3) Name of dietary ingredient: See Attached Product Label
- 4) Brand Name: Men's PM Formula Over 40
- 5) Substantiation information on file at the company office. The corporate officer who can certify same is Dr. Doug Metz, Vice President.

Yours truly,

Dr. Doug Metz

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Vice President



MEN'S PM FORMULA - Over 40 is free of wheat, corn, dairy, sucrose, starch, sait and yeast.

CAUTION/WARNING: Keep out of reach of children. As with any supplement, herb or medication, do not provide it to a child without consulting a physician. Not for use by pregnant or lactating women unless directed by a chysician.

NOTE. This product is regulated by the FDA as a dietary supplement. If you have any questions about how you feel while taking this supplement, contact your physician. If you are taking any medication, have any disease or liness, consult your physician before taking this product for its stop or change prescribed medication without the permit on a prescription of your physician.

TOPACIE Keep tightly closed in a cool cryptate.

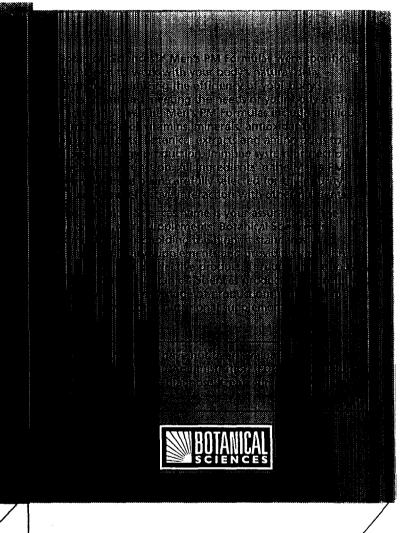
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DISTRIBUTED BY

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## SUPPLEMENT FACTS

Serving size: 2 packets (six tablets) Servings per container: 30		
Six Tablets Provide:	Amt/Serving	% Daily Value
Vitamin A (as beta-carotene)  Vitamin C (as ascorbic acid 100 mg, calcium ascorbate 100 mg, magnesium 100 mg,	.5000 IU	100%
palmitate 25 mg, potassium 50 mg, sodium 25 mg)	.400 ma	667%
Calcium (as amino chelate 125 mg and calcium Citrimal 125 mg)		
Niacin (as niacinamide, granular)	.125 mg	625%
Folate (as folic acid)	.200 mca	50%
Biotin	.200 mcg	67%
lodine (from Atlantic kelp)	.150 mcg	100%
Magnesium (as amino chelate buffered)		
Zinc (as zinc Chelazome® amino chelate)	.20 mg	.,133%
Selenium (as L-selenomethionine)	.100 mcg	143%
Copper (as copper Chelazome® amino chelate)	.2 mg	100%
Manganese (as manganese Chelazome® amino chelate )		
Chromium (as chromium Chelavite® amino chelate)	.100mcg	83%
Alpha-ketoglutaric acid	.62.5 ma	•
Alpha-lipoic acid	.500 mcg	
Apple pectin	.100 ma	*
Betatene®-mixed carotenoids (Dunaliella salina plant, std 7.5% mixed carotenoids)	.6,300 mcg	
Bilberry extract (Baccinium myrtillus fruit, 4:1)	.15 mg	*******
Calcium d-saccharate	.25 mg	·····
Calcium pyruvate	.50 mg	
Cat's claw extract (Uncaria tomentosa bark, 4:1)	.100 mg	<b>*</b>
Citrus bioflavonoid complex	.125 mg	······································
Damiana extract (Turnera diffusa leaf 4:1)	. 75 mg	
Fructo-oligosaccarides		
Ginger extract (Zingiber officinale root, 4:1)		
Grape seed extract (Vitis vinifera seed, std 95% proanthocyanidins) Grape skin extract (Vitis vinifera skin, 4:1)	mg	
Hawthorn berry extract (Crataegus coneata fruit 4:1)		
L-Lysine	33 mg	*
1-Taurine		*
Lutein extract,	50 ma	
iycopene,	50 mg	*
Milk thistle extract (Silybum marianum seed, std 80% silymarin)		
Muira puama extract (Ptychopetali lignum root, 4:1)		
N-Acetyl cysteine		
PABA	.50 mg	*
Pinebark extract (Pinus strobus bark, std 95%)	15 mg	
Pygeum extract (Pygium africum plant, 4:1)	40 mg	*
Red wine extract (Vitis vinifera fruit, std 15%)	25 mg	.,
RoseOx® rosemary extract (Rosmarinus officianalis leaf, std 6% carnosic acid)	25 mg	
Saw palmetto extract (Serona repens fruit, std 25% liposterolics)		
Turmeric extract (Curcuma longa root, std 95% curcuminoids)	100 mg	
Vegetable phytonutrient complex (vegetable extract: broccoli, cabbage, carrots, parsley leaf, tomatoes,	250	
peppermint, barley grass, beets)	. ∡ɔʊ mg	
<ul> <li>Daily Value not established</li> <li>Other ingredients: Gelatin, cellulose, calcium phosphate hydrous, stearic acid, magnesium sfearate and silico Albion Laboratories, U.S. Patents 4,599,152 and 5,292,729 and patents pending. Chelazome® and Chelavite® of Albion Laboratories, Inc. Betatene® is a registered trademark of Henkel Corp. RoseOx® is a registered tra Corp. Botanical Sciences,<sup>188</sup>, the human figure symbols, and American Specialty Health &amp; Wellness<sup>188</sup> are licen Specialty Health &amp; Wellness.</li> </ul>	are registered trade demark of Hauser Cl	nemical



## **AM-PM Formulas**

Men's and women's AM-PM formulas contain a blend of vitamins, minerals and herbs specifically formulated to work with your body's natural daily rhythms, so that nutrients are available when the body needs them most.